

156. The system of claim 13 wherein the means for positioning comprises a movable platform on which the means for optically exciting and means for detecting are mounted.

REMARKS

Claims 13-35, 55-59, 79-82, 87-92, and 118-155 are pending in the abovereferenced application. Claims 13, 87, 122, 128 and 152 have been amended to specify that
the light source is positioned to excite the sample during at least a portion of the temperature
cycling, and that the detector operates to detect fluorescence during at least a portion of the
temperature cycling. The amendments to these claims are made simply in response to the
Examiner's concerns to clarify the meaning of "monitoring the reaction in real time." Claims
87 and 122 have been further clarified by deleting the term "in real time" from these claims.
Dependent claim 123 has been amended to be consistent with the amendments to claim 122,
from which claim 123 depends. No change in scope is intended by way of these amendments.
Support for the amendments to claims 13, 87, 122, 128 and 152 is found throughout the
specification, for example on page 76, line 4 to page 77, line 8 and Figure 11.

Claims 13 and 128 have also been amended for clarification to point out more particularly that the means for positioning operates on the sample container. Support for these amendments is found throughout the specification, for example on page 66, lines 8-14, and page 76, line 17 to page 77, line 1.

The following claims have been amended to correct informalities. Claim 14 has been amended to delete subject matter duplicated in dependent claim 15. Claims 24 and 136 have been amended to specify that the means for optically exciting the sample impinges

the first side of the sample container and claims 25 and 137 have been amended to specify that the means for detecting detects radiation emitted from the second side of the sample container. Support for the amendments to claims 24, 25, 136, and 137 is found in figure 19H and claim 31, as originally filed. Claim 28 has been amended to depend from claim 14, rather than claim 13. Claims 33 and 145 have been amended to clarify that each sample container is <u>formed for</u> holding less than 1 ml of a sample and the carousel is <u>formed for</u> holding the sample containers. Claim 55 has been amended to use terms consistently and to correct grammatical errors. Claim 120 has been amended to correct a typographical error. No narrowing of scope is intended by way of any of these amendments.

No new matter is added by way of any of the amendments.

New claim 156 depends from claim 13 and specifies that the optics are mounted on a movable platform. Support for new claim 13 is found at page 147, line 19 to page 148, line 1 and figure 32. No new matter is added by way of new claim 156.

Claims 13-32, 122, 124-144, 152-153, and 155 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the Applicants regard as their invention. In particular, the Examiner notes that these claims recite "in real time" in their preambles, and the Examiner requests clarification regarding what is meant by this phrase. Claims 122 and 152 have been amended to delete the phrase "in real time." Furthermore, independent claims 13, 122, 128, and 152 have been amended to clarify that the light source is positioned to excite or illuminate the sample during at least a portion of the temperature cycling, and that the detector detects fluorescence during at least a portion of the temperature cycling. Claims 14-32 depend from claim 13, claims 124-127 depend from claim 122, claims 129-144 depend from claim 128, and

claims 153 and 155 depend from claim 152. Thus, all rejected claims have been amended to clarify the phrase "in real time." Withdrawal of this rejection is respectfully requested.

Claims 13, 18, 20, 28, 128, 129, and 140 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over either Jerman (U.S. Patent No. 5,824,204) or Schnipelsky (U.S. Patent No. 5,229,297).

Applicants respectfully submit that Jerman is not prior art for purposes of the present application. Jerman issued on October 28, 1998, after the filing date of the present application (June 4, 1997). While Jerman has a filing date of June 27, 1996, prior to the filing date of the present application, the June 27, 1996 filing date of Jerman is subsequent to the priority date of the present application. In particular, the present application claims priority from U.S. Patent Application No. 08/658,993, filed June 4, 1996, now abandoned. The subject matter of claims 13, 18, 20, 28, 128, 129, and 140 is fully described in the '993 application (see, for example, pages 23-45, 55-61 and 135-136, and claims 2-3). Specifically, the sample container is described at page 35, line 3-14 and page 38, line 20 to page 39, line 20; the positioning means is described at page 57, lines 4-15; the means for heating and means for cooling are described at page 23, line 14 through page 25, line 14, page 29, lines 9-22 and page 55, line 23 to page 56, line 15; the control means is described at page 25, lines 15-25; the means for optically exciting the sample during at least a portion of the temperature cycling is described at page 57, line 16 to page 58, line 19 and page 64, line 19 to page 65, line 12; and the means for detecting the fluorescence during at least a portion of temperature cycling is described at page 58, line 20 to page 60, line 22 and page 64, line 19 to page 65, line 12. Additionally, for claim 18, the sample container fabricated at least partially from glass is described at page 29, lines 24-25, and the sample container having a volume not greater than 10,000 ml is described at page 39, lines 15-16; for claim 20, the means for positioning the

means for optically exciting the sample and the means for detecting the fluorescence of the sample to optimize the fluorescence detected is described at page 63, line 19 to page 65, line 17; for claim 28, the means for determining at least one reaction parameter is described at 136, line 5 to page 137, line 20; for claim 128, means for determining at least one reaction parameter and means for adjusting the control means is described at page 136, lines 5-11, line 20; for claim 129, altering the times for heating and cooling is described at 136, line 5 to page 137, line 20; and for claim 140, the means for determining at least one reaction parameter is described at 136, line 5 to page 137, line 20; for claim 128. Because the '993 application was filed before the filing date of Jerman, Jerman is not prior art for purposes of the present invention.

As amended, claims 13, 18, 20, 28, 128, 129, and 140 are directed to a system for performing PCR and monitoring the reaction in real time wherein the system comprises a sample container and means for positioning the sample container in a monitoring position. Schnipelsky discloses a closed system for performing PCR wherein the sample is moved between reaction compartments that are in fluid communication. The detection compartment 40 of Schnipelsky is a flow-by compartment (col. 12, lines 36-37), through which flows a solution containing amplified nucleic acid material (col. 13, lines 11-13). Furthermore, in the Schnipelsky device, the solution flows to the detection compartment subsequent to PCR amplification (col. 14, line 10).

Rather than the flow-by device of Schnipelsky, the systems of claims 13, 18, 20, 28, 128, 129, and 140 comprise a sample container and a means for positioning the sample container in a monitoring position. Furthermore, as clarified by the amendments to claims 13 and 128, claims 13 and 128 (as well as dependent claims 18, 20, 28, 129, and 140) are directed to embodiments wherein fluorescence is detected during at least a portion of thermal cycling

when the sample is in a monitoring position. Thus, claims 13, 18, 20, 28, 128, 129, and 140 are directed to systems wherein exciting the sample and monitoring fluorescence may occur during and/or subsequent to temperature cycling. Schnipelsky simply does not teach or suggest any means for positioning the sample, and detection in Schnipelsky can only occur subsequent to amplification. Thus, a substitution of fluorescence detection for the optical detection of Schnipelsky would not result in the present invention. Applicants respectfully submit that claims 13, 18, 20, 28, 128, 129, and 140 are not rendered obvious by the disclosure

Because Jerman is not prior art for purposes of the present invention and Schnipelsky does not teach or suggest the claimed invention, withdrawal of the § 103 rejection is respectfully requested.

Finally, Applicants submit herewith a corrected sheet 6 of 7 of PTO Form 1449, listing the correct publication date for Reference ET.

The amendments and remarks presented herein are intended to fully address each of the Examiner's objections/rejections. In light of the amendments and remarks, the applicants respectfully request allowance of the pending claims and passage of the application to issuance.

Respectfully submitted,

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of Schnipelsky.